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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,374	12/21/2001	Chandrashekhar Pathak	SBI-082-CIP	2758

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EXAMINER	
AZPURU, CARLOS A	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,374	PATHAK, CHANDRASHEKHAR	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/09/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the request for continued prosecution and information disclosure statement filed 08/09/2006.

Specification

The information referring to the continuing data is incomplete and should be updated. Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15, 20-23, and 32 –33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Vitamin E derivatives of claims 13 and 15 do not have support in the original specification.

The stents of claims 20-23 having the "struts which comprise capillaries, grooves and channels engraved in the struts" or having "surface enhancing features" is not supported by the original specification.

The limitation of claims 32-33 having three layers wherein two layers comprise different biologically active agents have no support in the original specification.

Claims 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vitamin E, does not reasonably provide enablement for all derivatives of Vitamin E. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification sets out Vitamin E at page 15, line 5. However, no vitamin E derivatives are contemplated other than Vitamin E acetate.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for completely coating the stent, does not reasonably provide enablement for "at least some" coating. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification describes the coating as "completely encapsulating" the structure at page 13, lines 29-30.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending Application No. 10/446,916 (US'916). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'916 claims a coated stent comprising a HMG-Coa reductase inhibitor (see claim 1) at a concentration of between about 1 – 50 wt%. The carrier percentage would therefore be between 50-99% wt%. Multiple layers are disclosed at claims 32-33. While the claims do not set out a melting point of about 50 C or less, the instant claims do set out Vitamin E and other oils (see claims13-16) which the ordinary practitioner can easily identify as a carrier with a melting point of less than 50 C without undue experimentation As such, the ordinary practitioner would have found expected similar therapeutic results from the

use of the instantly claimed coated stent. Those of ordinary would have therefore found the instant stent obvious skill at the time of invention given the claims of US'916.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/397,778 (US'778). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'778 claims a coated stent having a biodegradable carrier with a melting point of less than 50 C. The instant claims contain carrier such as Vitamin E and other oils which have a melting point of less than 50 C (See claims13-16). Further, the carrier range of 50-99.9% is broad enough that anyone of ordinary skill given the claim of US'778 would have expected similar therapeutic results form the instant invention. As such, the instant claim would have been obvious to one of ordinary skill at the time of invention given the claim of US'778.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-11, 17-19, 24, 27-33 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 734 721 (EP'721).

EP'721 suggests a coating for stents which include multi-layer coatings at col. 7, lines 35-38. Biodegradable polymers for use in the formation of these layers is suggested at col. 5. lines 35-41. Specific polymers such as poly lactide are found in this citation. As claimed herein, lactide is a polymer having a melting point of less than 50 C. A reinforcement layer which is biostable and acts as an adhesive layer is disclosed at col. 6, lines 36-48. A rate controlling layer can also be placed above the layer containing the bioactive as disclosed at col. 6, lines 17-19. The combination of different drugs in a layer is contemplated by the reference by the statement of claim 3. HMG CoA reductase inhibitors and other anti-proliferative agents are found at col. 4, lines 49-50. Drug loading may be up to 70% at col. 4, lines 24-26, which overlaps clearly with the instant claims which have1-50 % bioactive. Multiple biodegradable layers are taught at col. 6, lines 48-51. Melting points of the polymers contemplated are listed at col. 5, lines 24-41 and overlap with the ranges claimed. Hydrophobic and hydrophilic properties are determined by the particular polymer selected, and EP'721 appears to include both.

Viscosity and molecular weight are determined by the materials chosen and are inherent to them. As such, the instant claims are anticipated by EP'721.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carlos A. Azpuru
Primary Examiner
Art Unit 1615